REMARKS

Claims 1-44 are pending. Claims 1 and 2 are amended herein, without prejudice. Applicants disagree with all rejections and makes these claim changes only to expedite prosecution and move to allowance as soon as possible. No new matter has been added by the amendments, support therefore being found throughout the specification, including the Figures and claims, as filed. Favorable reconsideration in light of the remarks which follow is respectfully requested.

1. 35 U.S.C. §102 Rejections

Claim 1 is rejected under 35 U.S.C. §102(b) over U.S. Patent No. 4,976,688 to Rosenblum (hereinafter "Rosenblum"). Applicants respectfully traverse.

Applicants recite, in amended independent claim 1, a catheter comprising an elongate body, a distal section coupled to the body, a deflection mechanism comprising a pull wire operatively connected to the distal section, a longitudinally extending inner lumen defined by the body and the tip, and a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section by providing a variable fulcrum for the distal section. As set out, the distal section is deflectable upon application of an external force by a user via the pull wire, and is linear absent application of an external force by a user via the pull wire.

Rosenblum describes a type of bending system for a catheter. In particular Rosenblum describes a flexible catheter connected to wires that can be manipulated to provide the catheter with a bend.

However, Rosenblum clearly fails to teach or suggest a catheter that comprises both a deflection mechanism and a curvature-adjustment mechanism as provided in Applicants' claim 1. In particular, Rosenblum at least does not teach or suggest a curvature adjustment-mechanism, in addition to the bending system, that adjusts the

radius of curvature of the distal section by providing a variable fulcrum for the distal section.

As such, it is respectfully submitted that claim 1 is patentable over Rosenblum. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §103 Rejections

Rosenblum, Middleton, Winnie and Sylvanowicz

Claims 2-5 are rejected under 35 U.S.C. §103(a) over Rosenblum in view of U.S. Patent No. 5,231,989 to Middleman et al. (hereinafter "Middleman"), U.S. Patent No. 3,856,009 to Winnie (hereinafter "Winnie"), or U.S. Patent No. 4,935,017 to Sylvanowicz (hereinafter "Sylvanowicz"). Applicants respectfully traverse.

As set out above in connection with claim 1, Rosenblum describes a flexible catheter connected to wires that can be manipulated to provide the catheter with a bend. Rosenblum at least fails to teach or suggest a curvature adjustment-mechanism that adjusts the radius of curvature of the distal section by providing a variable fulcrum for the distal section.

With respect to dependent claims 2-5, the Office acknowledges that Rosenblum at least does not teach or suggest a catheter elongate stiffener tube that is slidable longitudinally relative to the body and providing a fulcrum spaced a distance from the distal end of the distal section.

However, the Office points to Middleman, Winnie or Sylvanowicz as allegedly disclosing stiffeners. The Office asserts that it would have been obvious to a person of ordinary skill in the art to modify Rosenblum with a stiffener

> …in view of the proven conventionality of these enhancements, and moreover, because the addition of a stiffener would have

> enhanced the maneuverability of the catheter system by providing a more efficient curve adjustment mechanism.

Applicants respectfully traverse.

Rosenblum describes one type of bending system for a catheter. In particular Rosenblum uses a flexible catheter connected to wires that can be manipulated to provide the catheter with a bend or without a bend. Middleman, Winne and Sylvanowicz each individually describe a second type of bending system for a catheter. There is absolutely no teaching or suggestion, other than Applicants' present disclosure, to combine two alternative types of bending systems, or why two different systems that are designed and described to do the same thing would even be combined.

In particular, Middleman describes a steerable cannula comprising a cannula 22, an elastic member 24 for bending the cannula, and a straightener 26/40 for preventing the elastic member 24 from bending the cannula. As set out, the elastic member 24 has two general configurations: its bent shape and a substantially straight shape (see col. 2, lines 6-8). In particular, the elastic member 24 is provided with a pre-formed bent shape that the distal end 30 of the cannula takes on when the elastic member 24 is in its bent shape. The straightener 26 is used to force the elastic member 24 into its straight shape configuration, and, thus, also force the distal end 30 of the cannula from a bent configuration into a straight configuration.

Thus, Middleman describes a two-component bending system that must be used together so as to alternate between bent and straightened catheter configurations: (a) the elastic member 24 is required to provide the catheter with a bend, while (b) the straightener 26/40 is required to provide the catheter in a straight configuration.

There is absolutely no teaching or suggestion to combine Middleman's bending system with that of Rosenblum, each of which are designed to and described to

accomplish the same thing.

Winnie describes a catheter having a precurved distal portion 14. According to Winnie, an anti-skive device 60 can be slid over the precurved distal portion 14 so as to temporarily straighten it out so that after the precurved distal portion 14 is straight, an introducer needle 30 is advanced therethrough (see col. 5, line 65 – col. 6, line 5). By straightening out the precurved distal portion 14, the anti-skive device 60 eliminates the possibility that the introducer needle 30 will "skive" or cut away thin layers of the internal wall of the precurved distal portion 14. Thus, Winnie describes a device wherein a precurved member is straightened from a pre-formed curve to a straight configuration using a straightening member. As such, similar Middleton, Winnie describes a two-component bending system that includes (a) a stiffening portion (the anti-skive device) and (b) a pre-formed curved portion (in this case, the precurved distal portion) which must be used together so as to alternate between bent and straightened configurations.

There is absolutely no teaching or suggestion to combine Winnie's bending system with that of Rosenblum, each of which are designed to and described to accomplish the same thing.

Sylvanowicz describes a catheter system that includes a catheter 10 having a predetermined curve at its distal end 14, and an outer sheath 28 having sufficient stiffness such that as it is advanced over the distal end, it straightens the predetermined curve (see col. 1, line 60 – col. 2, line 3; col. 3, lines 23-25; col. 4, lines 10-13). Thus, similar to Middleman and Winnie, Sylvanowicz describes a two-component bending system that includes (a) a stiffening portion (the outer sheath) and (b) a pre-formed curved portion (in this case, the pre-determined curve at the distal end) which are used together so as to alternate between bent and straightened configurations.

There is absolutely no teaching or suggestion to combine Sylvanowicz's bending

system with that of Rosenblum, each of which are designed to and described to accomplish the same thing.

Clearly, none of the cited references teach or suggest a Applicants' catheter which is provided with both (1) a deflection mechanism for manipulating the distal end of a catheter between a bent and straightened configuration as desired, and (2) a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section by providing a variable fulcrum for the distal section, as recited in independent claims 1 and 15. Further, there is absolutely no teaching or suggestion to combine and modify the references so as to provide Applicants' disclosed invention. As set out above, each of the references describes a type of bending system designed to do the same thing – alternate between a bent and straightened catheter distal end configuration. None of the references teach or suggest providing, in addition to a distal end deflection mechanism, a further and separate element which is a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section by providing a variable fulcrum for the distal section. Rather, this teaching comes purely from Applicants' disclosure. There is absolutely no teaching or suggestion, other than Applicants' present disclosure, to combine two alternative types of bending systems, or why two different systems that are designed and described to do the same thing would even be combined.

Thus, claim 1 is patentable over Rosenblum, Middleton, Winnie and Sylvanowicz. Claims 2-14 and 22-44 depend from claim 1 and, thus, also are patentable over Rosenblum, Middleton, Winnie and Sylvanowicz. Reconsideration and withdrawal of the rejections is respectfully requested.

Rosenblum, DeLaRama, Middleton, Winnie and Sylvanowicz

Claims 6-14 and 15-21 are rejected under 35 U.S.C. §103(a) over Rosenblum in view of U.S. Patent No. 5,381,782 to DeLaRama (hereinafter "DeLaRama"), and further in view of Middleton, Winnie and Sylvanowicz. Applicants respectfully traverse.

The Office acknowledges that Rosenblum does not disclose a distal section having a plurality of slots that provide collapsible spaces wherein the pull wire is attached to the distal end of the slotted tube. However, the Office asserts that this particular tube enhancement would have been considered conventional as evidenced by DeLaRama.

Without agreeing with or acquiescing to this assertion, Applicants respectfully submit that even if Rosenblum was combined with DeLaRama in view of Middleton, Winnie and/or Sylvanowicz, Applicants claimed catheters still would not be taught or suggested.

DeLaRama describes a catheter wherein, similar to Rosenblum, a pair of activation wires 58 are provided in connection with the tip member 44 such that application of tensile force on the activation wires causes the tip member 44 to bend (see, e.g. col. 5, line 30 - col. 6, line 7).

Thus, it is respectfully submitted that all of the cited references (Rosenblum, DeLaRama, Middleton, Winnie and Sylvanowicz) describes a type of bending system designed to do the same thing – alternate between a bent and straightened catheter distal end configuration. None of the references teach or suggest providing, in addition to a distal end deflection mechanism (pull cable in the case of Rosenblum and DeLaRama, or combination of pre-formed bent component/straightening component in the case of Middleton, Winnie and Sylvanowicz), a further and separate element which is a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section by providing a variable fulcrum for the distal section. Rather, this teaching comes purely from Applicants' disclosure. There is absolutely no teaching or suggestion, other than Applicants' present disclosure, to combine two alternative types of bending systems, or why two different systems that are designed and described to do the same thing would even be combined.

In view thereof, it is respectfully submitted that independent clams 1 and 15 are patentable over Rosenblum, DeLaRama, Middleton, Winnie and Sylvanowicz. Claims 16-14 and 16-21 depend from claim 15 and, thus, also are patentable over Rosenblum, DeLaRama, Middleton, Winnie and Sylvanowicz. Reconsideration and withdrawal of the rejections is respectfully requested.

Rosenblum, DeLaRama, Giba, Hanson, Brown, Greenwood, Sepetka, Naimark, West

Claims 22-35 are rejected under 35 U.S.C. §103(a) over Rosenblum, DeLaRama, U.S. Patent No. 5,876,373 to Giba (hereinafter "Giba"), U.S. Patent No. 5,709,874 to Hanson (hereinafter "Hanson"), U.S. Patent No. 6,053,900 to Brown (hereinafter "Brown"), U.S. Patent No. 5,004,455 to Greenwood (hereinafter "Greenwood"), U.S. Patent No. 5,882,334 to Sepetka (hereinafter "Sepetka"), U.S. Patent No. 7,455,657 to Naimarkh (hereinafter "Namark"), or U.S. Patent No. 5,318,525 to West (hereinafter West"). Applicants respectfully traverse.

The Office acknowledges that Rosenblum does not disclose the step of ejecting a therapeutically sufficient amount of agent into the body, a structure that is tissue, an organ, a cavty, or the heart. However, the Office asserts that Giba demonstrates the conventionality of using a steerable catheter of infusion of agents into the body. The Office further acknowledges that Rosenblum does not disclose the step of delivering agents into a bladder or urethra. However, the Office asserts that Hanson discloses the use of a catheter to deliver agents into the bladder or urethra. The Office further acknowledges that Rosenblum does not disclose the step of delivering agents comprising radiation. However, the Office asserts that Brown discloses the use of a catheter to delver an agent comprising radiation. The Office further acknowledges that Rosenblum does not disclose the step of delivering agents comprising antibiotics. However, the Office asserts that Greenwood discloses the use of a catheter to deliver an agent comprising an antibiotic. The Office further acknowledges that Rosenblum does not disclose the step of delivering agents comprising ethanol. However, the Office asserts that Sepetka discloses the use of a

catheter to deliver an agent comprising ethanol. The Office further acknowledges that Rosenblum does not disclose the step of delivering agents comprising proteins or polypeptides. However, the Office asserts that Naimark discloses the use of a catheter to deliver agents comprising proteins or polypeptides. The Office further acknowledges that Rosenblum does not disclose the step of delivering agents comprising thermal energy. However, the Office asserts that West discloses the use of a catheter to deliver thermal energy.

Without agreeing with or acquiescing to this assertion, Applicants respectfully submit that even if Rosenblum was combined with DeLaRama, Giba, Hanson, Brown, Greenwood, Sepetka, Naimark, and West, Applicants' claimed catheters still would not be taught or suggested. In particular, as set forth above, none of the references teach or suggest providing, in addition to a distal end deflection mechanism, a further and separate element which is a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section by providing a variable fulcrum for the distal section. Rather, this teaching comes purely from Applicants' disclosure.

In view thereof, it is respectfully submitted that independent clams 1 and 15 are patentable over Rosenblum, DeLaRama, Giba, Hanson, Brown, Greenwood, Sepetka, Naimark, and West. Claims 22-25 depend from claims 1 and 15 and, thus, also are patentable over Rosenblum, DeLaRama, Giba, Hanson, Brown, Greenwood, Sepetka, Naimark, and West. Reconsideration and withdrawal of the rejections is respectfully requested.

Rosenblum, Muto, Bowe, DeLaRama, Giba, Hanson, Brown, Greenwood, Sepetka, Naimark, West

Claims 36-44 are rejected under 35 U.S.C. §103(a) over Rosenblum in view of U.S. Patent No. 4,512,765 to Muto (hereinafter "Muto"), U.S. Patent No. 6,592,581 to Bowe (hereinafter "Bowe"), and further in view of DeLaRama, and further in view of Giba,

Hanson, Brown, Greenwood, Sepetka, Naimark, or West. Applicants respectfully traverse.

The Office acknowledges that Rosenblum does not disclose the step of advancing a mechanical agent. However, the Office asserts that the use of catheters to advance mechanical agents would be considered conventional as evidenced by Muto or Bowe. The Office acknowledges that Rosenblum does not disclose the step of ejecting a therapeutically sufficient amount of agent into the body, a structure that is tissue, an organ, a cavity, or the heart. However, the Office asserts that Giba demonstrates the conventionality of using a steerable catheter for such infusion of agents. The Office acknowledges that Rosenblum does not disclose the step of delivering agents into a bladder or urethra. However, the Office asserts that Hanson discloses the use of a catheter to deliver agents into the bladder or urethra. The Office acknowledges that Rosenblum does not disclose the step of delivering agents comprising thermal energy. However, the Office asserts that West discloses the use of a catheter to deliver thermal energy.

Without agreeing with or acquiescing to this assertion, Applicants respectfully submit that even if Rosenblum was combined with DeLaRama, Giba, Hanson, Brown, Greenwood, Sepetka, Naimark, and West, Applicants' claimed catheters still would not be taught or suggested. In particular, as set forth above, none of the references teach or suggest providing, in addition to a distal end deflection mechanism, a further and separate element which is a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section by providing a variable fulcrum for the distal section. Rather, this teaching comes purely from Applicants' disclosure.

In view thereof, it is respectfully submitted that independent clams 1 and 15 are patentable over Rosenblum, Muto, Bowe, DeLaRama, Giba, Hanson, Brown, Greenwood, Sepetka, Naimark and West. Claims 36-44 depend from claims 1 and 15 and, thus, also are patentable over Rosenblum, Muto, Bowe, DeLaRama, Giba, Hanson, Brown,

Greenwood, Sepetka, Naimark and West. Reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

Reconsideration and allowance of the claims is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application. If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105** under order number 84825(47992).

Dated: September 15, 2010

Respectfully submitted,

By: /Lisa Swiszcz Hazzard/
Lisa Swiszcz Hazzard
Registration No.: 44,368
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 517-5512
Attorneys/Agents For Applicant